UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 6, 2006

MEMORANDUM

Subject: Efficacy Review for VigorOx SP-15 Antimicrobial Agent, EPA Reg. 65402-3; DP Barcode: D333468

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Applicant: FMC Corporation
Active Oxidants Division
1735 Market Street
Philadelphia, PA 19103

Formulation from the Label:

Active Ingredient(s)	% by wt.
Peroxyacetic acid	15.0
Hyrogen Peroxide	10.0
Other Ingredients	65.0
Total	100.00 %

I. BACKGROUND

This submission, received November 6, 2006, is an amended application to add a use for aseptic food processing operations to the label. The product is currently registered for a variety of uses including; sterilization, disinfection, food and non-food sanitization, and for biofouling and slime control in water systems. Included in this application are the following documents: MRID No. 469648-01 "Modification of the AOAC Sporicidal Method to Determine the Efficacy of Products Used in Aseptic Filling Applications". The study was conducted at ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. Study Director: Amy S. Jeske, B.S. Completion Date: October 17, 2006; and a draft label, dated October 23, 2006.

II. USE DIRECTIONS

This product may be used to achieve commercial sterility of food packaging prior to fill. Apply on the exterior and interior of food containers and closure systems (caps, seals, etc.). Apply 4000 to 6000 ppm peroxyacetic acid at a minimum temperature of 65°C. The solution must remain in contact with the packaging surface for a minimum of 20 seconds; longer contact times may be required in certain aseptic food processing lines. Rinse containers with sterile water prior to filling with processed food.

III. AGENCY STANDARD FOR PROPOSED CLAIM

In order to be labeled as a sterilant for use in aseptic food processing operations, the Agency recommends use of a modified Official Methods of Analysis of AOAC International, Official Method 966.04 Sporicidal Activity of Disinfectants test to demonstrate the sterilant efficacy of products. Sixty stainless steel carriers should be tested against spores of both *Bacillus subtilis* (American Type Culture Collection (ATCC) 19659) (*B. subtilis*) and *Clostridium sporogenes* (ATCC 3584) (C. *sporogenes*) on three samples representing three different batches of the product, one of which should be at least 60 days old. The use of stainless steel carriers is an Agency approved modification to this method and is intended to simulate the type of surfaces that will be treated in an aseptic processing operation. The product should kill the test spores on all the carriers.

IV. BRIEF DESCRIPTION OF THE DATA

Testing was conducted on three batches of the product, one of which was at least 60 days old. The product was diluted to 4000 ppm in filter sterilized deionized water. *B. subtilis* and *Clostridium sporogenes* were grown in soil extract nutrient broth and soil extract cooked meat medium, respectively. The carriers were screened prior to use, as prescribed in the AOAC Use Dilution Test, soaked overnight in 1N NaOH, washed in water until neutral and autoclaved in a 0.1% asparagines solution. The carriers were contaminated by immersing them for 15 minutes in a 72±4 hour old broth culture, at a ratio of 1 carrier per 1.0 mL of culture. The carrier-to-culture ratio is an Agency approved modification to this test, and is to increase the amount of inoculum on the carriers. A 4000 ppm dilution of the product was made by adding 40 mL of the disinfectant to 1460 mL of filter sterilized deionized water. Each contaminated carrier was placed in an individual tube of 10 mL of the diluted disinfectant, allowed to sit for 20 seconds, and then transferred to the primary subculture tube, containing 10 mL fluid thioglycollate medium with 0.1% sodium thiosulfate and 0.01% catalase. The carriers were then transferred to the secondary subculture tube, which contained fluid thioglycollate medium with 0.07% lecithin and 0.5% Tween 80. The subculture tubes were incubated for 21 days at 35-

37°C. A preliminary reading of the subculture tubes was conducted at day 9. Tubes demonstrating growth were subcultured to confirm the presence of the test organisms. At the completion of the 21 day incubation period, the subcultured tubes were visually examined for growth. Again, those tube demonstrating growth were subcultured onto the appropriate agar medium for confirmation of the test organisms. Those tubes with no growth were heat shocked for 20 minutes at 80±2°C and reincubated for 72±4 hours at 35-37°C. The heat shocked tubes were stored for 2 days at 2-8°C prior to reading the results. The following controls were employed in this test: purity, carrier sterility, neutralizing subculture medium sterility, viability, carrier quantitation, neutralization, and HCl.

V. RESULTS

Batch Number/Lot Number	Total Carriers Tested Per Organism	Organism	Carrier Count	No +/Number Tested
723511/60501-1	60	*Bacillus subtilis*	1.05×10^5	0/60
		Clostridium sporogenes	4.1×10^5	0/60
722365/60425-5 >60 days old	60	*Bacillus subtilis*	1.05×10^5	0/60
		Clostridium sporogenes	4.1×10^5	0/60
726796/60517-13	60	*Bacillus subtilis*	1.05×10^5	0/60
		Clostridium sporogenes	4.1×10^5	0/60

VI. CONCLUSIONS

The submitted data appear to support the use of the product, Vigorox SP-15 Antimicrobial Agent, as a sterilant to achieve commercial sterility in validated facilities when used at a contact time of 20 seconds at 65°C against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584).

VII. RECOMMENDATIONS

1. On page 3 of the label under the heading "Aseptic food Processing Operations", revise the statement "Apply 4000 to 6000 ppm peroxyacetic acid . . . . " to read, "Apply 4000 ppm peroxyacetic acid. . . ." This product was only tested at 4000 ppm.

2. Also under the heading "Aseptic food Processing Operations", remove the second paragraph and replace it with the following: "This product may be used on food packaging as an aseptic packaging antimicrobial rinse in a food processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21CFR parts 108, 110, 113 and/or 114. Use in an aseptic food processing operation includes testing required for the process validation."